

Harmonization of diagnoses for Acute Myocardial Infarction identification from different databases in the SAFEGUARD project



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CONFLICT OF INTEREST

- The research leading to these results has received funding from the European Community's Seventh Framework Programme (FP7/2007-2013 under grant agreement n° 282521 – the SAFEGUARD project.
- C. Varas-Lorenzo as employee of RTI Health Solutions participates in project advisory boards funded by pharmaceutical companies.
- M. Sturkenboom is head of an academic unit that conducts research for pharmaceutical companies: Pfizer, Lilly, AstraZeneca, Boehringer Ingelheim.

BACKGROUND

- Collaborative studies utilizing multiple healthcare databases (DBs) are increasing in the area of drug safety studies.
- However, an essential step in combining several types of DBs across different countries is to investigate, benchmark and harmonize event definitions and extraction.

OBJECTIVE

- To harmonize and compare incidence rates (IRs) and standardized incidence rates (SIRs) of acute myocardial infarction (AMI) diagnoses among different DBs from European countries and the USA.

METHODS

- Data was retrieved from 9 DBs from 6 Western countries participating in the Safety Evaluation of Adverse Reactions in Diabetes (SAFEGUARD) project:
 - Netherlands (IPCI, PHARMO)
 - Italy (HSD, Regional DBs of Lombardy and Puglia)
 - Germany (GePaRD)
 - Spain (BIFAP)
 - UK (CPRD)
 - USA (Medicare) (only subjects aged 65 years and over)
- Each DB covers different study periods between 1999 and 2012, depending on data availability, and comprises different types of data sources (electronic medical records or record linkage systems).
- Code mapping and harmonization of event extraction was performed to obtain homogeneous queries from different coding systems (ICD-9-CM, ICD-10-GM, READ and ICPC combined with free text).
- Data was extracted locally from each DB without applying any restriction or exclusion criteria and processed using standardized software (Jerboa), providing age and gender specific IRs and SIRs, using the WHO population as reference population, for MI per 100,000 person-years (PYs).

RESULTS

- From a source population of 35,279,358 subjects, 364,151 incident MI diagnoses during the study period were identified in 239,591,637 PYs.
- Rates increased with age in all DBs, especially above age 45 years for males and above 60 years for females (**Figure 1 and 2**).
- Except for two DBs showing quite high estimates, SIRs ranged from 46 to 114 for general practice DBs and from 59 to 126 for administrative DBs.
- For all ages and across DBs, the age specific IRs were higher for males than females (**Figure 1 and 2**).

Figure 1. Incidence Rates of AMI diagnoses by age for Males

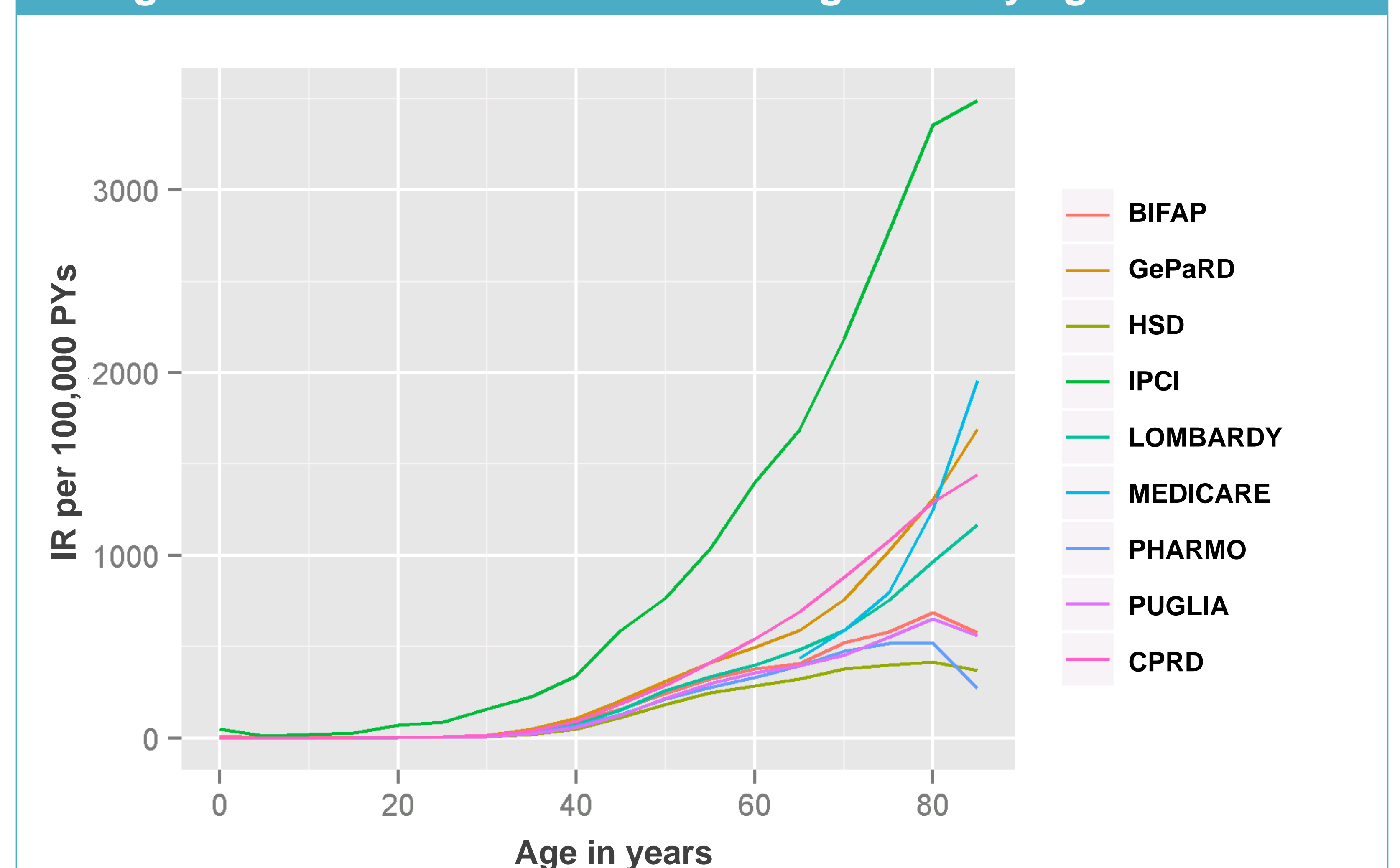
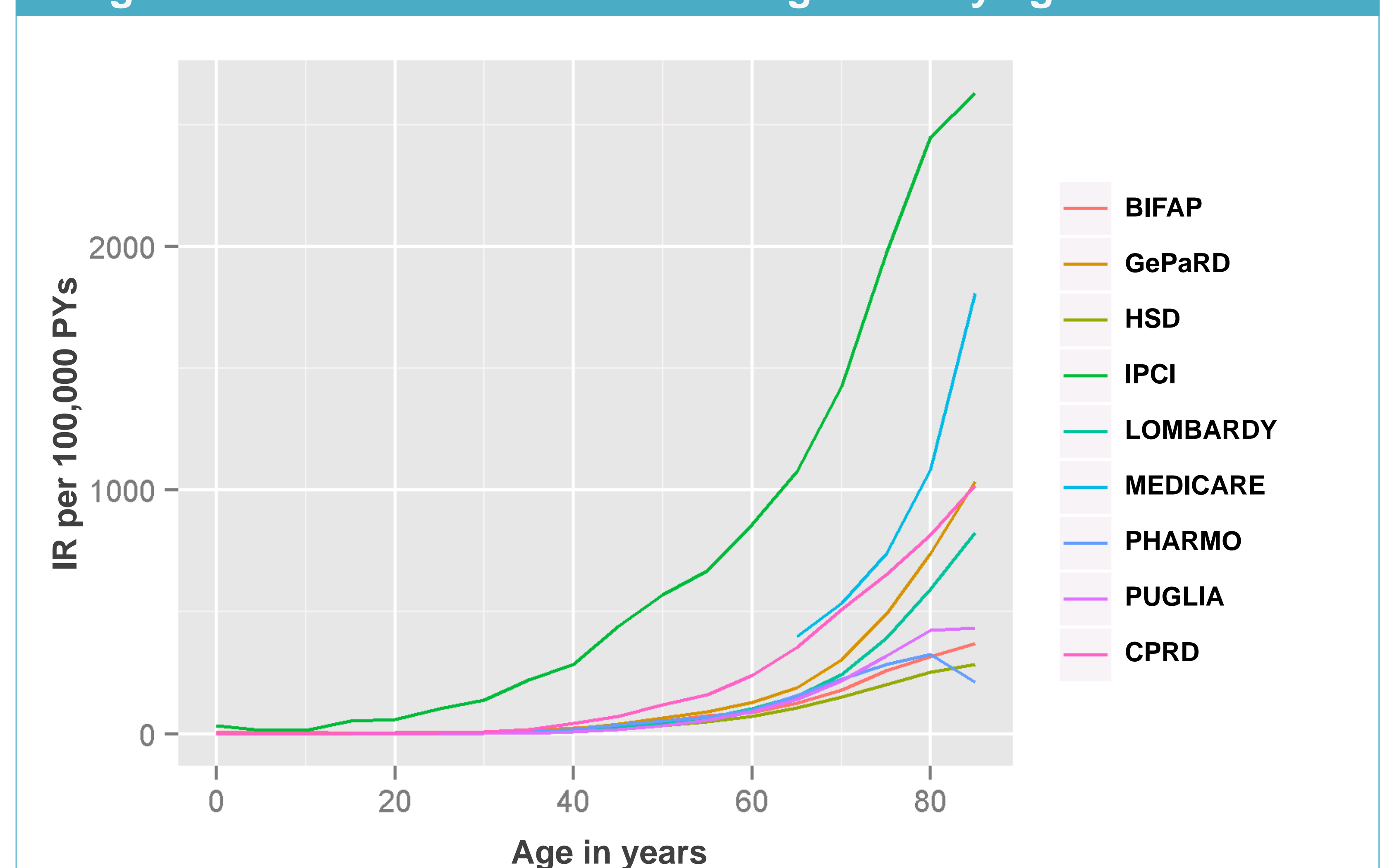


Figure 2. Incidence Rates of AMI diagnoses by age for Females



CONCLUSIONS

- Code mapping and harmonization of potential AMI event extractions is important to understand differences between databases.
- Large heterogeneity across DB was observed, as expected, but harmonization is essential prior to implement drug safety multi-database studies.